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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/488,298 01/20/00 LUTZ

0 3874-128 US

EXAMINER

HM12/1204

Mary Kakefuda Esq.  
Mathews Collins Shepherd & Gould P.A.  
100 Thanet Circle  
Suite 306  
Princeton NJ 08540

KIM, J

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

12/04/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.

09/488,298

Applicant(s)

LUTZ ET AL.

Examiner

Jennifer M Kim

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: \_\_\_\_\_.

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#### DETAILED ACTION

Applicants' election with traverse of etoposide in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the compositions of the present invention are directed to the class of podophyllotoxin compounds in compositions and that the search should be conducted using "podophyllotoxin" as the compound and should not be required to select a particular podophyllotoxin compound. This is not found persuasive because the claims are drawn to an astronomical number of compounds through out the class 514. For example, beta-D-glucoside compound such as etoposide in subclass 27+, podophyllotoxin subclass 463, azatoxin subclass 287, and ellipticine subclass 285 et seq.

Therefore, it is clear that an undue burden will be placed on the examiner especially in the pharmaceutical literature search in the examination of the claims.

It is noted that this is not a species election, these inventions are distinct and independent for the reasons given above and have acquired a separate status in the art because of

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their recognized divergent classification, restriction for examination purposes as indicated is proper.

Therefore, the claims have been examined only to the extent of applicants' election.

*Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1-5, 7, 10, 16, 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Amselem (U.S. Patent No. 5891469) of record.

Amselem at the abstract, column 3, lines 60-65, column 4, lines 7-16, and lines 55-60, column 5, lines 31-43, lines 55-

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58, column 6, lines 9-20, column 13, Example 11, and column 14, claims 13, 20, and 22, teach Applicants' claimed composition use for treating mammal with various diseases.

*Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 6, 8-9, 11-13, 15, 17, and 21 rejected under 35 U.S.C. 103(a) as being unpatentable over Amselem (U.S. Patent No 5891469) and Brandely et al. (1991:663504).

Amselem teach additon to above rejection, at column 3, lines 17-22, column 4, lines 7-13, and column 14, claim 12, teach the anticancer drug etoposide comprising surfactants such

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as tocoferol(TPGS), dispersion adjuvant(PVP) and a hormone in a micelle formulation.(See claims 9, 14-16, and 21).

Amselem also teach at column 6, lines 43-48, teach the range of TPGS set forth in claim 11 and applicants upper range of TPGS set forth in claims 12-13.

Brandely et al. at the title, teach the use of polypeptide in a pharmaceutical composition for the treatment of cancer.

The difference between applicants' invention and the primary reference is that lack of polypeptide and a peptide set forth in claims 8 and 17.

However, as stated in In re Kerkhoven, 626 f.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 f.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 f.2d 274, 276-277, 126 USPQ 186, 188 (ccpa 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

In this application it would have been prima facie obvious to combine Etopside composition, above and polypeptide conjointly to treat cancer.

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For the reasons above, the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is (703) 308-2232. The examiner can normally be reached on Monday through Friday from 9 AM. to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Theodore J. Criares  
Primary Examiner  
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jmk  
November 22, 2000